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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,852	04/03/2001	Jay M. Short	INVIT1250-4	4596

7590

06/13/2003

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EXAMINER

TRAN, MY CHAU T

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 06/13/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant No.

09/825,852

Applicant(s)

SHORT, JAY M.

Examiner

My-Chau T. Tran

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1 and 3-9, drawn to a method for identifying a complex (a morphatide) from a library of complexes (morphatides) wherein the morphatide comprises a scaffolding component, a linker component, and an agent molecule, classified in class 435, subclass 435.
 - II. Claims 2, 5, and 7, drawn to a method for identifying a complex (a morphatide) from a library of complexes (morphatides) wherein the morphatide comprises a scaffolding component and an agent molecule (*Note this method differ from Group I, by not reciting a linker*), classified in class 435, subclass 6.
 - III. Claims 10-13 and 15, drawn to a method of generating modified scaffolding components, classified in class 436, subclass 55.
 - IV. Claim 14, drawn to a method of identifying a **different morphatide**, classified in class 436, subclass 91.
 - V. Claim 16, drawn to a method of separating scaffolding components with attached linker components from the agent molecules of the previously identified morphatide, classified in class 435, subclass 3.
 - VI. Claim 17-18, drawn to a composition comprising a conjugated morphatide and a pharmaceutically acceptable carrier, classified in numerous subclasses of classes 532-570 series depending on the structure of the molecule.

- VII. Claims 19-21, drawn to a composition comprising a morphatide conjugated to a therapeutic agent, classified in numerous subclasses of classes 514 series depending on the structure of the molecule.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Groups I, II, III, IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions as claimed have different method steps that have different functions, different effects, and modes of operation.

The method step of preparing a library of morphatides comprised of a scaffolding component, a linker component, and an agent molecules of Group I is not required by the claims of Groups II-V. The method step of preparing a library of morphatides comprised of a scaffolding component and an agent molecule of Group II is not required by the claims of Groups I and II-V. The method step of generating modified scaffolding components of Group III is not required by the claims of Groups I-II and IV-V. The method step of reconnecting the scaffold component of Group IV is not required by the claims of Groups I-III and V. The method step of reattaching agent molecules to the new scaffolding components of Group V is not required by the claims of Groups I-IV.

3. Inventions of Groups VI, VII, and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

Art Unit: 1639

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions as claimed have different functions and different effects.

The morphatide compound of Group VI is not required by the claims of Groups VII-VIII. A composition comprising a morphatide and a pharmaceutically acceptable carrier of Group VII is not required by the claims of Groups VI and VIII. A composition comprising a morphatide conjugated to a therapeutic agent of Group VIII is not required by the claims of Groups VI-VII.

4. Inventions of Groups VI-VII (product) and I-V (process) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product (a morphatide) as claimed can be used in a materially different process of using that product. For example a "morphatide" consisting of a lipid scaffold, an ethanolamine linker a fluorescent agent molecule could be used as a probe for membrane fluidity measurements or a morphatide.

5. Because these inventions are distinct for the reasons given above and the searches required are not co-extensive thus requiring a burdensome search, restriction for examination purposes as indicated is proper. Additionally, different patentability considerations are involved for each group. For example, a patentability determination for Group VII would involve a determination of the patentability of the combination of a composition comprised of a morphatide and a pharmaceutically acceptable carrier (independent of its use) while a

Art Unit: 1639

patentability determination for Group I would involve a consideration of the patentability of a method for identifying a complex (a morphatide) from a library of complexes (morphatides) wherein the morphatide comprises a scaffolding component, a linker component, and an agent molecule. These considerations are very different in nature.

Even though some of the groups are classified in the same class/subclass, this has no effect on the non-patent literature search. Different groups would require completely different searches in non-patent databases, and there is no exception that the searches would be co-extensive.

6. This application contains claims directed to the following patentably distinct species of the claimed invention.

7. If applicants elect the invention of **Group I (Claims 1, and 3-9)**, applicants are required to further elect *one* species from *each* of the following group of species:

- a. One single species of a scaffold. (Applicants are requested to *provide the structure of the elected scaffold*)
- b. Specific “linker” and number of “linkers”. (Applicants are requested to *provide the structure of the “linker”*)
- c. Specific “agent” and number of “agent”. (Applicants are requested to *provide the structure of the “agent”*)
- d. One single species of target.
- e. Specific mode of interaction with the target.
- f. Specific mode of separating the “morphatide”.

Base on the election of species (a), (b), and (c) the selection of the number and/or type of "linker" and/or "agent" must include the point and/or means of attachment to a particular scaffold that would results in a morphatide.

The selection of the number and/or type of "linker" and/or "agent" and the point and/or means of attachment to a particular scaffold results in a morphatide, which have different chemical structure and/or physiochemical properties and would be capable of separate manufacture and/or use; and would necessitate different and separately burdensome manual and computer bibliographic and structure searches in both patent and non-patent areas. Further for the different methods, the steps are different, requiring different reagents and/or producing different products/results.

Accordingly, applicants are hereby required to elect **a single morphatide composition with chemical structure** from among the compounds listed in the specification for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

For this response to be complete and for search purposes, applicants should provide the chemical structure of elected compounds or composition or species, wherein each specific formula substituents of each of the above identified elected species are defined either by picture, or by expressing the species in terms of the variables of the formula.

Applicant is advised that a response to the above election requirement should include an identification of the species that are elected consonant with these requirements, and a listing of all claims readable thereon, including any claims subsequently added. If available, a drawing which corresponds to the elected compound should be provided to the Examiner in order to

Art Unit: 1639

expedite the search of the elected compound species. An argument that all claims are generic is considered nonresponsive unless accompanied by an election.

8. If applicants elect the invention of **Group II (Claims 2, 5, and 7)**, applicants are required to further elect *one* species from *each* of the following group of species:

- a. One single species of a scaffold. (Applicants are requested to *provide the structure of the elected scaffold*)
- b. Specific “agent” and number of “agent”. (Applicants are requested to *provide the structure of the “agent”*)
- c. One single species of target.
- d. One single mode of interaction with the target.
- e. Specific mode of separating the “morphatide”.

Base on the election of species (a), and (b) the selection of the number and/or type of “linker” and/or “agent” must include the point and/or means of attachment to a particular scaffold that would results in a morphatide.

The selection of the number and/or type of “agent” and the point and/or means of attachment to a particular scaffold results in a morphatide, which have different chemical structure and/or physiochemical properties and would be capable of separate manufacture and/or use; and would necessitate different and separately burdensome manual and computer bibliographic and structure searches in both patent and non-patent areas. Further for the different methods, the steps are different, requiring different reagents and/or producing different products/results.

Art Unit: 1639

Accordingly, applicants are hereby required to elect **a single morphatide composition with chemical structure** from among the compounds listed in the specification for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

For this response to be complete and for search purposes, applicants should provide the chemical structure of elected compounds or composition or species, wherein each specific formula substituents of each of the above identified elected species are defined either by picture, or by expressing the species in terms of the variables of the formula.

Applicant is advised that a response to the above election requirement should include an identification of the species that are elected consonant with these requirements, and a listing of all claims readable thereon, including any claims subsequently added. If available, a drawing which corresponds to the elected compound should be provided to the Examiner in order to expedite the search of the elected compound species. An argument that all claims are generic is considered nonresponsive unless accompanied by an election.

9. If applicants elect the invention of **Group III (Claims 10-13 and 15)**, applicants are required to further elect *one* species from *each* of the following group of species:

- a. One single species of a scaffold. (Applicants are requested to *provide the structure of the elected scaffold*)
- b. Specific “linker” and number of “linkers” (if present on the scaffold). (Applicants are requested to *provide the structure of the “linker”*)
- c. Specific “agent” and number of “agent”. (Applicants are requested to *provide the structure of the “agent”*).

Art Unit: 1639

d. One single species of the “second agent” (regarding claim 13). (Applicants are requested to *provide the structure of the “agent”*)

e. One single species of the “linker” for reconnecting the scaffold and agent (regarding claim 15). (Applicants are requested to *provide the structure of the “linker”*)

Base on the election of species (a), (b), and (c) the selection of the number and/or type of “linker” and/or “agent” must include the point and/or means of attachment to a particular scaffold that would results in a different morphatide.

The selection of the number and/or type of “linker” and/or “agent” and the point and/or means of attachment to a particular scaffold results in a morphatide, which have different chemical structure and/or physiochemical properties and would be capable of separate manufacture and/or use; and would necessitate different and separately burdensome manual and computer bibliographic and structure searches in both patent and non-patent areas. Further for the different methods, the steps are different, requiring different reagents and/or producing different products/results.

Accordingly, applicants are hereby required to elect **a single morphatide composition with chemical structure** from among the compounds listed in the specification for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

For this response to be complete and for search purposes, applicants should provide the chemical structure of elected compounds or composition or species, wherein each specific formula substituents of each of the above identified elected species are defined either by picture, or by expressing the species in terms of the variables of the formula.

Applicant is advised that a response to the above election requirement should include an identification of the species that are elected consonant with these requirements, and a listing of all claims readable thereon, including any claims subsequently added. If available, a drawing which corresponds to the elected compound should be provided to the Examiner in order to expedite the search of the elected compound species. An argument that all claims are generic is considered nonresponsive unless accompanied by an election.

10. If applicants elect the invention of **Group IV (Claim 14)**, applicants are required to further elect *one* species from *each* of the following group of species:

- a. One single species of a scaffold. (Applicants are requested to *provide the structure of the elected scaffold*)
- b. Specific “linker” and number of “linkers”. (Applicants are requested to *provide the structure of the “linker”*)
- c. Specific “agent” and number of “agent”. (Applicants are requested to *provide the structure of the “agent”*)

Base on the election of species (a), (b), and (c) the selection of the number and/or type of “linker” and/or “agent” must include the point and/or means of attachment to a particular scaffold that would results in a morphatide.

The selection of the number and/or type of “linker” and/or “agent” and the point and/or means of attachment to a particular scaffold results in a morphatide, which have different chemical structure and/or physiochemical properties and would be capable of separate manufacture and/or use; and would necessitate different and separately burdensome manual and

Art Unit: 1639

computer bibliographic and structure searches in both patent and non-patent areas. Further for the different methods, the steps are different, requiring different reagents and/or producing different products/results.

Accordingly, applicants are hereby required to elect **a single morphatide composition with chemical structure** from among the compounds listed in the specification for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

For this response to be complete and for search purposes, applicants should provide the chemical structure of elected compounds or composition or species, wherein each specific formula substituents of each of the above identified elected species are defined either by picture, or by expressing the species in terms of the variables of the formula.

Applicant is advised that a response to the above election requirement should include an identification of the species that are elected consonant with these requirements, and a listing of all claims readable thereon, including any claims subsequently added. If available, a drawing which corresponds to the elected compound should be provided to the Examiner in order to expedite the search of the elected compound species. An argument that all claims are generic is considered nonresponsive unless accompanied by an election.

11. If applicants elect the invention of **Group V (Claim 16)**, applicants are required to further elect *one* species from *each* of the following group of species:

- a. One single species of a scaffold. (Applicants are requested to *provide the structure of the elected scaffold*)

Art Unit: 1639

b. Specific "linker" and number of "linkers". (Applicants are requested to *provide the structure of the "linker"*)

c. Specific "agent" and number of "agent". (Applicants are requested to *provide the structure of the "agent"*)

Base on the election of species (a), (b), and (c) the selection of the number and/or type of "linker" and/or "agent" must include the point and/or means of attachment to a particular scaffold that would results in a different morphatide.

The selection of the number and/or type of "linker" and/or "agent" and the point and/or means of attachment to a particular scaffold results in a morphatide, which have different chemical structure and/or physiochemical properties and would be capable of separate manufacture and/or use; and would necessitate different and separately burdensome manual and computer bibliographic and structure searches in both patent and non-patent areas. Further for the different methods, the steps are different, requiring different reagents and/or producing different products/results.

Accordingly, applicants are hereby required to elect **a single morphatide composition with chemical structure** from among the compounds listed in the specification for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

For this response to be complete and for search purposes, applicants should provide the chemical structure of elected compounds or composition or species, wherein each specific formula substituents of each of the above identified elected species are defined either by picture, or by expressing the species in terms of the variables of the formula.

Art Unit: 1639

Applicant is advised that a response to the above election requirement should include an identification of the species that are elected consonant with these requirements, and a listing of all claims readable thereon, including any claims subsequently added. If available, a drawing which corresponds to the elected compound should be provided to the Examiner in order to expedite the search of the elected compound species. An argument that all claims are generic is considered nonresponsive unless accompanied by an election.

12. If applicants elect the invention of **Group VIII (Claims 19-21)**, applicants are required to further elect *one* species from *each* of the following group of species:

a. A *single* type of therapeutic agent.

The species are distinct, each from the other, because their modes of action are different. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter.

For this response to be complete and for search purposes, applicants should provide the chemical structure of elected compounds or composition, wherein each specific formula substituents of each of the above identified elected species are defined either by picture, or by expressing the species in terms of the variables of the formula.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Art Unit: 1639

13. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

14. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the

Application/Control Number: 09/825,852

Page 15

Art Unit: 1639

organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct

June 11, 2003


PADMASIRI PONNALURI
PRIMARY EXAMINER